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APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
21-307**

Microbiology Review(s)

NOV 8 2000

Consultative Review for HFD-540
Division of Dermatologic and Dental Drug Products
Clinical Microbiology Review

Requester: Frank Cross
Date of Request: 10-11-00
Date Received by DAIDP: 10-12-00
Reason for Request: Clinical Microbiology Review of an NDA requesting Rx-to-OTC switch
IND/NDA Number: 21-307
Review Date: 10-26-00
Submission/Type: Original NDA
Document Date: 9-28-00
Assigned Date: 10-13-00
Applicant: Schering-Plough HealthCare Products
3 Oak Way
Berkeley Heights, NJ 07922
Contact Person: Mark Gelbert, Ph.D., JD
Vice President, Scientific Affairs
Schering-Plough HealthCare Products
3 Oak Way
Berkeley Heights, NJ 07922
Phone: (908) 679-1703
Drug Product Name:
 Proprietary: Mentax
 Nonproprietary/USAN: Butenafine HCl 1% cream
 Code Names/ #'s: KP-363
 Therapeutic Class: Antifungal
Pharmacological Category/Indication:
Butenafine HCl 1% cream is an antifungal agent for treatment of tinea pedis, tinea cruris, and tinea corporis.
Dosage Form: Topical cream
Strength(s): 1% Butenafine HCl in Propylene Glycol
Dicaprylate and Glycerin
Route of Administration: Topical
Dispensed: _____RX _____X_____OTC
Related Documents (if applicable):
IND ☒ NDA 20-524, NDA 20-663

REMARKS/COMMENTS


Butenafine HCl 1% cream is an FDA approved product for treatment of tinea pedis, tinea cruris, and tinea corporis. Under this submission the sponsor is requesting a switch from prescription status to over-the-counter status. Information concerning the safety and efficacy of butenafine HCl 1% cream for these indications was previously submitted to the Agency by Berneck Pharmaceuticals Inc. under IND ☒ NDA 20-524, and NDA 20-663.

The annotated labeling was submitted for review under this application. From a microbiological view the label for the carton of the "Athlete's Foot Cream" seems appropriate. The label for the "Jock Itch Cream" however, makes statements referring to the drug product being fungicidal. To be more clear, the statement _____ appears three times on the carton.

Butenafine HCl is a benzylamine derivative with a chemical structure and mode of action similar to that of the allylamine class of antifungals. Depending on the concentration of the drug and the fungal species tested, the allylamines may be fungistatic or fungicidal in vitro. At this time it is not known whether treatment with a fungicidal agent Vs a fungistatic agent has any clinical significance. Implying fungicidal activity is considered a marketing toll and should be removed from the label.

CONCLUSION & RECOMMENDATIONS:

From the microbiological viewpoint the label for the OTC product is approvable. The sponsor should be instructed to remove the phrase ' _____ ' from the carton label of the product for "jock Itch Cream."



Sousan Sayahtaheri Altaie, Ph. D.
Clinical Microbiology Review Officer

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HFD-520/Division File
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CD and Final Initialed 11/8/00 ASDP
TF 11/9/00